Pro - Choice Alliance for Responsible Research

November 17, 2006

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California Department of Health Services
Submitted by email

RE: Human Stem Cell Research (SB 322, SB 1260)
Proposed Statewide Guidelines for Human Stem Cell Research for Public Comment

Thank you for the opportunity to provide these comments on behalf of the Pro-Choice Alliance for Responsible Research.

Generally, we would suggest that the preamble state its intention to be consistent with the CIRM regulations *and* SB 1260. As noted the DHS guidelines will pertain to non-CIRM funded research which is the purview of SB1260. While the CIRM regulations and SB 1260 are generally consistent, these guidelines should first comport with the requirements of SB1260, and second, seek harmonization with CIRM regulations if there is any disparity between them. In particular, the DHS guidelines should better reflect the provisions of SB 1260 especially in the area of informing, informed consent, women's health, monitoring and data collection.

Banned activities:
We do not support the elimination of (f) "the transfer to a uterus of a genetically modified human embryo." While that language may need definition, it should be clear that such research is unacceptable. We would support legislation to make that clear, but believe the DHS guidelines should maintain that prohibition in the interim.

SCRO members:
In order to ensure proper oversight and minimize conflicts of interest, the majority of each SCRO should not be research scientists. Members can include nurses, doctors, lawyers, bioethicists, academics, and other experts in public health and women's health who are not also research scientists. The National Academies recommends at least one person from the community. Inclusion of a patient advocate is important, but they too have conflicts of interest and, therefore, the patient advocate representative is not a substitute for a community member. This diversity of views is critical to effective oversight. The language should be explicit. The UK's Human Fertilisation and Embryology Authority and the Canadian Institute for Health Research provide useful models for diverse membership: The Chair, Deputy Chair and at least half of the HFEA's governing board's 21 members must be neither doctors nor scientists involved in human embryo research or providing infertility treatment.

Data collection and monitoring:
Data collection is an important aspect of accountability, monitoring, enforcement, and quality. Only with good data collection and review will the state and the public be able to

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effectively evaluate this new science as it moves forward.

The DHS guidelines should incorporate all of the data collection and reporting requirements of SB 1260, and should require the reporting of the following:

1. summaries of proposed research activities that went before the SCRO and the IRB, and whether they were approved.

2. policies and procedures adopted by the SCRO.

3. an overview of *all* human stem cell research being done at the institution.

4. an overview of any failures to comply with these standards.

5. A summary of results, both positive and negative, of any non-CIRM-funded research or clinical trial.

6. Any significant adverse reactions in a clinical trial.

7. A disclosure of the personal, professional, and financial interests in biotechnology or biomedical companies of the SCRO members.

8. health outcomes of oocyte donors resulting from oocyte retrieval, including adverse health reactions resulting from ovarian stimulation.

9. Demographics of oocyte providers used in each stem cell line derived.

These records should be available to the public, with exceptions for the privacy of any patient who may be personally identifiable, or for proprietary intellectual property.

Guideline §7 (b)(2):
language should be revised to conform with SB 1260, “provide medical care required as a direct result of the procedure.”

Thank you.

Susan Berke Fogel